DEPARTMENT OF HEALTH & HUMAN SERVICES

549/1d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

September 8, 2004 W/L: 47-04

Robert Tapper
President
General Medical Company
1935 Armacost Avenue
Los Angeles, CA 90025-5210

Dear Mr. Tapper:

During an inspection of your establishment located in Los Angeles, California, from July 20, 21, and 29, 2004, United Stated Food and Drug Administration (FDA) Investigator, Kirtida Patel, determined that your firm manufactures and distributes DRIONIC® Long Term Antiperspirant For Hands & Feet, DRIONIC® Long Term Antiperspirant For Underarm Treatment, and DRIONIC® Special Applications Device For Amputee, Groin and Buttocks, all of which are intended to control sweat. These products are devices as defined by Section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your firm's procedures and practices are not in conformity with the Quality System (QS) regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting (MDR) regulation, Title 21 CFR Part 803. These violations of the QS and MDR regulations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act and misbranded within the meaning of Section 502(t)(2) of the Act.

Quality System Regulation

The investigator noted the following violations of the QS regulation:

1. Your firm failed to establish and maintain a quality system that is appropriate for the specific devices designed or manufactured, and that meets the requirements of the Quality System Regulation, as required by 21 CFR 820.5, and management with executive responsibility has not ensured that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR § 820.20(a). Specifically, your firm failed to adequately implement and document corrective and preventative actions, product non-conformance, and

complaints. Additionally, Device History Records are not reviewed for rejects and rework. [FDA 483, Item #1]

2. Your firm failed to document corrective and preventive action activities such as analysis of sources of quality data, investigations of causes of nonconformities, the actions needed to correct or prevent corrective actions, implementation of corrective and preventive actions, dissemination of information about quality problems or nonconforming product to responsible parties, and submission of information on quality problems and corrective actions for management review, as required by 21 CFR 820.100(b). [FDA 483, Item #2]

3. Your firm failed to review, evaluate, and investigate complaints involving the possible failure of a device to meet its specifications, as required by 21 CFR 820.198(c). For example, your complaint records do not include the details of the complaint and you do not provide a reasoning or justification supporting decisions that investigation of complaints is unnecessary. In addition, the complaints you have received for shock, blisters/burn, rash, irritation, lump in the armpit, and lightheadedness have not been reviewed, evaluated, and investigated. [FDA 483, Item #3]

4. Your firm failed to adequately implement complaint handling procedures for receiving, reviewing and evaluating complaints to ensure they are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1). [FDA 483, Item #5]

5. Your firm failed to document the evaluation and investigation of nonconforming product, as required by 21 CFR § 820.90(a). [FDA 483, Item #7]

6. Your firm failed to conduct quality audits by individuals who do not have direct responsibility for the matters being audited, as required by 21 CFR 820.22. For example, the quality audit you performed on 4/13/04 was conducted by the Director of Engineering, who is directly responsible for the quality system and manufacturing. [FDA 483, Item #6]

7. Your firm failed to verify or validate changes to a specification, as required by 21 CFR 820.70(b). For example, you made four changes to the device specifications for the hands/feet and underarm devices without verifying or validating the changes. [FDA 483, Item #8]

8. Your firm failed to validate computer software for its intended use according to an established protocol prior to approval and issuance, and document the results of these validation activities, as required by 21 CFR 820.70(i). For example, software validation has not been performed for changes you made to the "CHECKSUM" system program. The "CHECKSUM" is used to measure the current output level for the final testing of the devices. [FDA 483, Item #9]

9. Your firm failed to maintain in the Device History Records (DHR) the acceptance records which demonstrate the device is manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184(d). For example, your DHR did not include acceptance records for the DRIONIC® Long Term Antiperspirant For Hands & Feet and the DRIONIC® Long Term Antiperspirant For Underarm Treatment. [FDA 483, Item #10]

10. Your firm failed to have sufficient personnel with the necessary training and experience to perform their jobs, as required by 21 CFR 820.25(a). For example, your appointed management representative has no documented training and experience in the quality system regulations. [FDA 483, Item #11]

11. Your firm failed to document employee training and to establish procedures for identifying training needs and to ensure that all personnel are adequately trained to perform their assigned responsibilities, as required by 21 CFR 820.25(b). [FDA 483, Item #12]

Medical Device Reporting

The investigator noted that there was a failure to comply with a requirement prescribed under Section 519 of the ACT as follows:

12. Your firm failed to implement in the Medical Device Reporting (MDR) procedures an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting, as required by 21 CFR 803.17(a)(2). Complaint files fail to adequately address MDR reporting requirements and criteria for reporting. [FDA 483, Item #4]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. Federal Agencies are advised of the issuance of all Warning Letters pertaining to medical devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. No premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken, or will take, to identify and correct the noted violations

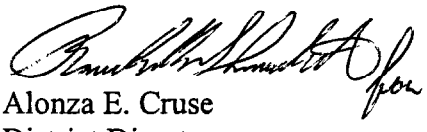
including (1) the time frames within which the corrections will be completed, (2) any documentation indicating that the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations will not recur.

If you have any questions regarding this letter, please contact Mariza M. Jafary, Compliance Officer at 949-608-2977.

Your written reply should be addressed to:

Pamela Schweikert
Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2446

Sincerely,



Alonza E. Cruse
District Director

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
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Sacramento, CA 94234-7320